

**REMARKS**

Claims 17-55 are withdrawn by the Examiner as being drawn to a non-elected invention. Claims 2-3 and 13-14 are withdrawn by the Examiner as being drawn to a non-elected species. Claims 1, 4-12 and 15-16 are examined.

**Claim rejection - 35 USC 112, first paragraph**

Claims 1, 4-12 and 15-16 are rejected under 35 USC 112, first paragraph for lack of written description in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner states that there is “no definition as to what constitutes a precursor or what makes a precursor of a binding partner.”

Applicants disagree with the Examiners contention that the term “precursor” is not adequately described in the specification. In the last paragraoph of page 4 of the specification U.S. Patent No. 5,877,007 (the ‘007 patent) is referenced and incorporated by reference. Example 5 of ‘007 describes precursor peptides in relation the human insulin receptor. In addition, the applicants cite to *Principals of Biochemistry*, 2<sup>nd</sup> Ed. by Lehninger, Nelson and Cox, Worth Publishing, New York, NY 1993. This is a standard introductory text that is well known to one skilled in the art. On page 908 of this text, stages of protein synthesis are discussed and stage 5 is categorized as folding and processing. Specifically, “Before or after folding the new polypeptide may undergo enzymatic processing to remove one or more amino acids, . . .” The text goes on to describe the various types of modification that may occur. As the Examiner admits at the top of page 4 of the Office Action, the definition of the term precursor is not at issue. So, in light of the above references, one skilled in the art would have no difficulty in understanding what a “precursor peptide” is.

In reference to claim 1 of the present application, binding to a target is used to identify a "... binding partner, or binding partner precursor ..." and in the specification a binding partner precursor is described as a "polypeptide which may be modified post-translationally." The goal of the present invention is to identify peptide binding partners. These partners may be either the mature protein or it's presursor. The Applicants assert that, given the definition in the specification, the discussion in the '007 patent and the Lehninger reference cited above, it is well within the ability of one of ordinary skill in the art to fully understand the structure of and to identify a binding partner precursor. Therefore when one skilled in the art reads the specification and claims of the present invention, they would conclude that the applicants were in full possession of the invention as claimed and as required by 35 USC 112, first paragraph. Applicants respectfully request withdrawal of the rejection.

**Claim rejection - 35 USC 112, second paragraph**

Claims 1, 4-12 and 14-16 are rejected under 35 USC 112, second paragraph for being indefinite for failing to particularly point out and distinctly claim the subject matter which the subjects regard as their invention. In responding to the Applicants arguments the Examiner states that the definition of the naturally occurring binding partner in the specification and the language of claim 1 are at odds. Specifically, at page 5 lines 30-31 the term gene products is defined as encompassing any post translation modifications while claim 1 makes reference to "... the naturally occurring binding partner or partner precursor, ..."

Defining gene products to "encompass any post translational modifications" broadens the meaning of the term gene products, not restricts it. A synonym of encompass is include. By including post translational modifications we are not excluding proteins that do not

have these modifications. Therefore the definition of gene products that is in the specification includes both binding partners and partner precursors as used in claim 1.

In responding to the applicants arguments about the use of the "consisting essentially of about" language in claims 7 and 8, the Examiner states that the phrase is unclear or not positively recited in the specification (page 7 of the Office Action). The Applicants respectfully point out that the phrase "consisting essentially of" has an accepted meaning as defined in section 2111.03 of the MPEP and that the random sequences of 20 (claim 7) or 40 (claim 8) amino acids are explicitly recited at the bottom of page 14 of the specification and in Example 1. This is in addition to the ranges of 10 – 50 amino acids and 20 – 40 amino acids that are explicitly recited at the bottom of page 13 of the specification. The applicants respectfully request that the rejection be withdrawn.

#### **Claim Rejection - 35 USC 102**

Claims 1, 4-12 and 14-16 are rejected under 35 USC 102(a) as being anticipated by Blume et. al. Biopolymers (Peptide Science) 55:347-356, 2000. The Applicants respectfully point out that this application claims priority to U. S. Application No. 60/202,912 filed May 9, 2000. The Applicants have previously submitted a copy of the Blume publication and a copy of an email from Steve Drew of the publisher of the article, John Wiley & Sons Ltd. The Examiner correctly points out that the bibliographic information on the first page of the publication indicates a publication year of 2000. The Applicants respectfully point out that the first page also clearly indicates that the first publication was online in February of 2001 and that the Copyright year was 2001 not 2000. The 2001 publication date is confirmed by the email from Steve Drew which states that the publication was actually released to the public on February 6, 2001. The Applicants respectfully assert that the Blume article was not available to the public

before the priority date of May 9, 2000 and as such is not proper prior art under 35 USC 102(a).

The Applicants respectfully request that the rejection be withdrawn.

Claims 1, 4-12 and 14-16 are also rejected under 35 USC 102(b) as being anticipated by Kraft (J. Biological Chemistry, 274:1979-85, 1999). The applicants have previously presented arguments that Kraft does not teach the finding of "naturally occurring binding partners". In responding to these arguments the Examiner states that the Applicants arguments are "not commensurate in scope with the claims" since the claims do not recite the need for a biological relevance of the naturally occurring binding partner. In addition the Examiner believes the Applicants further arguments that the sequence peptides disclosed by Kraft do not resemble the natural partners are "nothing more than conclusory statements without any evidentiary support."

The Applicants strongly disagree with the Examiners assertions. Applicants claims do recite the need for biological relevance and claim 1 does require that the gene product possess the motif be identified "as the naturally occurring binding partner . . ." The statement in Kraft that "the possible biological relevance of such homologies remains unknown . . ." runs directly counter to the above stated limitation of claim 1. Identifying sequences with no known biological relevance is not the object of the present invention. Further, the evidentiary support for the conclusory statements is present in Kraft itself. That the DLxxL peptides do not compete for the  $\beta 6$  binding site on the  $\alpha v$  chain is found at page 1984, right column, line 14. Also, Kraft et. al. reports that the motifs identified do not look like the naturally occurring binding partner fibronectin. Page 1984 in the second paragraph of the discussion. Finally, in the last paragraph of the discussion, Kraft concludes "At present we have no indication, where, if at all, the XX-DLxxLx sequences play a biological role with  $\alpha v\beta 6$  integrin." Clearly, Kraft et. al., by their

own statements, do not believe they have found a "naturally occurring binding partner" as defined by the present invention. Since Kraft does not teach all of the limitations of the present invention Applicants respectfully request withdrawal of the rejection.

### **Claim Rejections – 35 USC 103**

Claims 1, 4-12 and 14-16 are rejected under 35 USC 103(a) as being unpatentable over Kraft in view of Kay et. al. (6,303,574). As argued above, Kraft does not teach identifying a naturally occurring binding partner, nor does Kay. In the Examiners response to the Applicants arguments it is stated that Kay is relied on to support that the length of the random peptide can be varied. Applicants respectfully submit that Kay does not remedy the lack of disclosure of a naturally occurring binding partner in Kraft. In addition, the Examiner has not cited a motivation for combining Kay with Kraft. Since neither reference teaches identifying a naturally occurring binding partner, Applicants assert that there is no motivation to combine. As neither Kraft or Kay, alone or in combination, teach the identification of a naturally occurring binding partner, Applicants respectfully request withdrawal of the rejection.

### **CONCLUSION**

Based on the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejection of claims and allowance of this application.

### **AUTHORIZATION**

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. 13-4500, Order No. 2598-4004US1. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

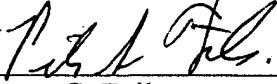
In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to

grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2598-4004US1. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,  
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Dated: September 23, 2004

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